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(Original Signature of Member)

109TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To amend the Public Health Service Act to expand the scope of information required for the data bank on clinical trials of drugs, and for other purposes.

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**IN THE HOUSE OF REPRESENTATIVES**

M\_\_\_\_. \_\_\_\_\_ introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To amend the Public Health Service Act to expand the scope of information required for the data bank on clinical trials of drugs, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Fair Access to Clinical  
5       Trials Act”.



1 **SEC. 2. CLINICAL TRIALS DATA BANK.**

2 (a) IN GENERAL.—Title IV of the Public Health  
3 Service Act (42 U.S.C. 281 et seq.) is amended—

4 (1) in section 402, by striking subsection (j);  
5 and

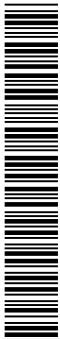
6 (2) by inserting after section 402 the following  
7 section:

8 **“SEC. 402A. CLINICAL TRIALS DATA BANK.**

9 “(a) IN GENERAL.—

10 “(1) DATA BANK.—The Secretary, acting  
11 through the Director of NIH, shall establish, main-  
12 tain, and operate a data bank of information on clin-  
13 ical trials (including premarket and postmarket  
14 trials) for drugs, biological products, and devices.  
15 The activities of the data bank shall be integrated  
16 and coordinated with related activities of other agen-  
17 cies of the Department of Health and Human Serv-  
18 ices, and to the extent practicable, coordinated with  
19 other data banks containing similar information.

20 “(2) CONSULTATION.—The Secretary shall es-  
21 tablish the data bank after consultation with the  
22 Commissioner of Food and Drugs, the directors of  
23 the appropriate agencies of the National Institutes  
24 of Health (including the National Library of Medi-  
25 cine), and the Director of the Centers for Disease  
26 Control and Prevention.



1 “(b) COLLECTION AND DISSEMINATION OF INFORMA-  
2 TION.—

3 “(1) COLLECTION.—In carrying out subsection  
4 (a), the Secretary shall collect, catalog, store, and  
5 disseminate the information described in such sub-  
6 section.

7 “(2) INCLUSION OF SUBMITTED INFORMA-  
8 TION.—All information on clinical trials required in  
9 this section to be submitted to the Secretary shall be  
10 included in the data bank as soon as practicable  
11 after the Secretary receives the information, subject  
12 to the provisions of this section.

13 “(3) DISSEMINATION.—The Secretary shall dis-  
14 seminate information in the data bank through in-  
15 formation systems, which shall include toll-free tele-  
16 phone communications available to members of the  
17 public, to health care providers, and to researchers.

18 “(c) TRIALS SUBJECT TO REQUIREMENTS.—

19 “(1) TRIALS OF SAFETY AND EFFECTIVE-  
20 NESS.—All clinical trials, whether federally funded  
21 or privately funded, conducted to test the safety or  
22 effectiveness (including comparative effectiveness) of  
23 a drug, biological product, or device (whether clinical  
24 trials of approved products or unapproved products)



1 are subject to the requirements of this section, ex-  
2 cept as provided in paragraph (2).

3 “(2) EXCEPTIONS.—The requirements of para-  
4 graph (1) do not apply to any of the following:

5 “(A) A clinical trial to determine the safe-  
6 ty of a use of a drug if the trial is designed  
7 solely to detect major toxicities in the drug or  
8 to investigate pharmacokinetics, except that the  
9 requirements of such paragraph do apply if the  
10 trial is designed solely to investigate pharmaco-  
11 kinetics in a special population or populations.

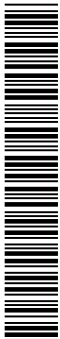
12 “(B) A small clinical trial to determine the  
13 feasibility of a device, or a trial to test proto-  
14 type devices where the primary focus is feasi-  
15 bility.

16 “(3) CERTAIN TRIALS.—The data bank may in-  
17 clude information on a clinical trial described in sub-  
18 paragraph (A) or (B) of paragraph (2) with the con-  
19 sent of the responsible person for the trial.

20 “(4) RULE OF CONSTRUCTION.—This section  
21 may not be construed as applying to any classified  
22 information (as defined in subsection (1)).

23 “(d) REQUIRED INFORMATION.—

24 “(1) REGISTRATION OF TRIAL.—



1           “(A) IN GENERAL.—Before commencing a  
2           clinical trial that is subject to subsection (c)(1),  
3           the responsible person for the trial shall register  
4           the trial with the Secretary. Such a registration  
5           shall be in such form and be submitted in such  
6           manner as the Secretary requires, and shall in-  
7           clude the following information:

8                   “(i) The medical condition being stud-  
9                   ied.

10                  “(ii) A scientific title for the trial that  
11                  includes the name of the intervention, the  
12                  condition, and the outcome being studied.

13                  “(iii) A statement of whether the trial  
14                  has undergone research ethics review. The  
15                  statement shall provide the date on which  
16                  approval was obtained pursuant to such re-  
17                  view, or shall provide that such review is  
18                  pending. In the case of a pending review,  
19                  when approval is obtained, the responsible  
20                  person shall provide an update that pro-  
21                  vides the date of the approval.

22                  “(iv) The anticipated start date for  
23                  the trial.



1 “(v) The purpose of the trial, includ-  
2 ing a statement of the interventions and  
3 comparisons involved.

4 “(vi) The eligibility criteria for par-  
5 ticipation in the clinical trial.

6 “(vii) The funding source or sources  
7 of the trial.

8 “(viii) A statement that—

9 “(I) identifies the product as an  
10 unapproved product or as an approved  
11 product, as applicable; and

12 “(II) in the case of an approved  
13 product, identifies the trial as inves-  
14 tigating the approved use of the prod-  
15 uct or an unapproved use of the prod-  
16 uct, as applicable.

17 “(ix) The estimated completion date  
18 for the trial. For purposes of this section,  
19 the term ‘completion date’ means the date  
20 of the final collection of data from subjects  
21 in the trial for the outcomes described in  
22 clause (vi).

23 “(x) A description of the primary and  
24 secondary outcomes to be examined in the  
25 trial, the time at which the primary and



1 secondary outcomes will be assessed, and  
2 the dates and details of any revisions to  
3 such outcomes.

4 “(xi) A statement of the hypothesis  
5 being tested in the trial.

6 “(xii) The total number of subjects  
7 anticipated to participate in the trial.

8 “(xiii) Contact information for the  
9 person to whom scientific inquiries regard-  
10 ing the trial should be made.

11 “(xiv) Information on—

12 “(I) study design;

13 “(II) methods;

14 “(III) study phase; and

15 “(IV) study type.

16 “(xv) If the trial will test the effec-  
17 tiveness of the use of a product with re-  
18 spect to a serious or life-threatening dis-  
19 ease or condition, the additional informa-  
20 tion described in subparagraph (B)(i).

21 “(xvi) With respect to an individual  
22 who is not an employee of the responsible  
23 person for the trial or of the manufacturer  
24 of the product involved, information on any  
25 agreement that the responsible person or



1 manufacturer has entered into with such  
2 individual that restricts in any manner the  
3 ability of the individual to—

4 “(I) discuss the results of the  
5 trial at a scientific meeting or any  
6 other public or private forum; or

7 “(II) publish the results of the  
8 trial, or a description or discussion of  
9 the results of the trial, in a scientific  
10 or academic journal.

11 “(xvii) After the initial submission of  
12 the registration, periodic updates to reflect  
13 changes to information provided under this  
14 subparagraph. Such updates—

15 “(I) shall be provided not less  
16 frequently than once every six months  
17 until information on the results of the  
18 trial is submitted under paragraph  
19 (2)(A) or a waiver is provided under  
20 paragraph (2)(D); and

21 “(II) shall identify the dates on  
22 which the changes were made.

23 “(B) SERIOUS OR LIFE-THREATENING DIS-  
24 EASES.—





1           “(i) IN GENERAL.—For a clinical trial that  
2           will test the effectiveness of the use of a prod-  
3           uct with respect to a serious or life-threatening  
4           disease or condition, the additional information  
5           referred to in subparagraph (A)(xv) is the fol-  
6           lowing:

7                   “(I) A brief summary of the trial, pro-  
8                   vided in lay language.

9                   “(II) A description of the location of  
10                  trial sites and the start date of the trial.

11                  “(III) A point of contact for individ-  
12                  uals desiring to enroll as subjects in the  
13                  trial, including a single point of contact for  
14                  all trial sites.

15                  “(IV) The status of the trial with re-  
16                  spect to the enrollment of subjects, stated  
17                  for the trial in general and for individual  
18                  trial sites.

19                  “(V) Information that may be  
20                  available—

21                   “(aa) under a treatment inves-  
22                   tigational new drug application, or a  
23                   treatment investigational device ex-  
24                   emption, that has been submitted to  
25                   the Secretary under section 561(c) of



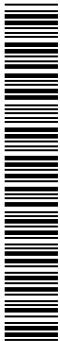
1 the Federal Food, Drug, and Cos-  
2 metic Act (relating to expanded access  
3 protocols); or

4 “(bb) as a Group C cancer drug  
5 (as defined by the National Cancer  
6 Institute).

7 “(ii) **FORMATTING FOR GENERAL PUB-**  
8 **LIC.**—The information provided under clause (i)  
9 shall be in a format that can be readily  
10 accessed and understood by members of the  
11 general public, including patients seeking to en-  
12 roll as subjects in clinical trials.

13 “(C) **LABELS OF APPROVED PRODUCTS.**—If a  
14 clinical trial registered under subparagraph (A) is  
15 investigating an approved product and the label for  
16 such product is included on the Internet site of the  
17 Food and Drug Administration, the information in  
18 the data bank concerning the trial shall include an  
19 electronic link to such label for individuals accessing  
20 the data bank through the Internet.

21 “(D) **UNIQUE IDENTIFIER.**—The Secretary  
22 shall assign to each clinical trial registered under  
23 subparagraph (A) a unique identifier for purposes of  
24 the data bank. The Secretary shall seek to ensure



1       that such identifiers comply with international  
2       standards for identifying clinical trials.

3           “(E) MODIFICATIONS REGARDING REQUIRED  
4       INFORMATION.—Notwithstanding clauses (i) through  
5       (xvi) of subparagraph (A), requirements under such  
6       clauses may be modified by the Secretary, and addi-  
7       tional requirements for the provision of information  
8       in registrations under such subparagraph may be es-  
9       tablished by the Secretary, in order to ensure the  
10      nonmisleading disclosure of important information  
11      from clinical trials.

12           “(2) SUBMISSION OF RESULTS OF TRIAL.—

13           “(A) IN GENERAL.—The responsible per-  
14      son for a clinical trial that is subject to sub-  
15      section (c)(1) shall provide to the Secretary in-  
16      formation described in subparagraph (B) on the  
17      results of the trial, subject to subparagraph  
18      (D). The information shall be provided in the  
19      form of a structured abstract and in such man-  
20      ner as the Secretary may require, in a form not  
21      likely to mislead or distort the results.

22           “(B) INFORMATION.—For purposes of sub-  
23      paragraph (A), the information described in  
24      this subparagraph on the results of a clinical  
25      trial is the following:



1           “(i) The actual completion date of the  
2 trial and the reasons for any difference  
3 from such actual date and the estimated  
4 completion date submitted pursuant to  
5 paragraph (1)(A)(ix), or, if the trial is ter-  
6 minated prior to completion, the termi-  
7 nation date and reasons for such termi-  
8 nation.

9           “(ii) Primary and secondary out-  
10 comes, presented succinctly as quantitative  
11 data and as tests of hypotheses.

12           “(iii) Information on the number and  
13 type of significant adverse events in sub-  
14 jects that may be associated with the prod-  
15 uct involved, including such events for  
16 which a causal relationship has not been  
17 established.

18           “(iv) A citation to each covered article  
19 published in a peer-reviewed scientific or  
20 academic journal. An article published in  
21 such a journal is a covered article for pur-  
22 poses of this clause if—

23                   “(I) the article discusses the re-  
24 sults of the trial;



1 “(II) the responsible person or  
2 the principal investigator for the clin-  
3 ical trial contributed to the article;  
4 and

5 “(III) MEDLINE includes a ci-  
6 tation to the article.

7 “(v) A description of the process used  
8 to review the results of the trial, including  
9 a statement about whether the results have  
10 been peer reviewed by reviewers inde-  
11 pendent of the sponsor.

12 “(vi) If the trial is investigating an  
13 unapproved product or an unapproved use  
14 of an approved product, a statement, as  
15 appropriate, displayed prominently at the  
16 beginning of information in the data bank  
17 concerning the trial, that the Food and  
18 Drug Administration—

19 “(I) is currently reviewing an ap-  
20 plication for approval of such product  
21 or use to determine whether the use is  
22 safe and effective;

23 “(II) has disapproved an applica-  
24 tion for approval of such product or  
25 use;



1 “(III) has reviewed an applica-  
2 tion for approval of such product or  
3 use but the application was withdrawn  
4 prior to approval or disapproval; or

5 “(IV) has not reviewed or ap-  
6 proved such product or use as safe  
7 and effective.

8 “(vii) If data from the trial has not  
9 been submitted to the Food and Drug Ad-  
10 ministration, an explanation of why it has  
11 not been submitted.

12 “(viii) A statement providing such in-  
13 formation on the protocol for the trial as  
14 may be necessary to evaluate the results of  
15 the trial. Criteria issued by the Secretary  
16 under subsection (k) shall include criteria  
17 regarding information that is required for  
18 purposes of such statements.

19 “(ix) In the group of subjects receiv-  
20 ing the product, and in each comparison  
21 group of subjects, the percentage of indi-  
22 viduals who ceased participation as sub-  
23 jects and the reasons for ceasing participa-  
24 tion.



1           “(x) Basic demographic information  
2           on subjects.

3           “(xi) With respect to an individual  
4           who is not an employee of the responsible  
5           person for the trial or of the manufacturer  
6           of the product involved, information (to the  
7           extent not submitted under paragraph  
8           (1)(A)(xvi) on any agreement that the re-  
9           sponsible person or manufacturer has en-  
10          tered into with such individual that re-  
11          stricts in any manner the ability of the in-  
12          dividual to—

13               “(I) discuss the results of the  
14               trial at a scientific meeting or any  
15               other public or private forum; or

16               “(II) publish the results of the  
17               trial, or a description or discussion of  
18               the results of the trial, in a scientific  
19               or academic journal.

20               “(xii) After the initial submission of  
21               information on the results, periodic up-  
22               dates to reflect changes in the information  
23               submitted pursuant to this subparagraph.  
24               Such updates—



1 “(I) shall be provided not less  
2 frequently than once every six months  
3 during the 10-year period beginning  
4 on the date on which information on  
5 the results is due under subparagraph  
6 (C)(i); and

7 “(II) shall identify the dates on  
8 which the changes were made.

9 “(C) DUE DATE FOR RESULTS.—

10 “(i) IN GENERAL.—Information re-  
11 quired under subparagraph (A) on the re-  
12 sults of a clinical trial shall be submitted  
13 to the Secretary—

14 “(I) not later than one year after  
15 the earlier of—

16 “(aa) the estimated comple-  
17 tion date of the trial, as sub-  
18 mitted under paragraph  
19 (1)(A)(ix); or

20 “(bb) the actual completion  
21 date of the trial, or the actual  
22 date of the termination of the  
23 trial before completion, as appli-  
24 cable; or





1 “(II) by such later date as may  
2 apply under an extension under clause  
3 (iii).

4 “(ii) REPORTS REGARDING DUE DATE  
5 IN EXCESS OF THREE YEARS.—If the due  
6 date under clause (i) for information on  
7 the results of a clinical trial is a date that  
8 is more than three years after the date on  
9 which the trial was registered under para-  
10 graph (1)(A), the following applies:

11 “(I) Upon the expiration of such  
12 three-year period, the responsible per-  
13 son for the trial shall submit to the  
14 Secretary a report that describes the  
15 progress being made toward submis-  
16 sion of the results.

17 “(II) For each one-year period  
18 that lapses after the submission of the  
19 report under subclause (I), the re-  
20 sponsible person shall submit to the  
21 Secretary an additional report that  
22 describes such progress, except that  
23 no report is required under this sub-  
24 clause after such due date.

25 “(iii) EXTENSIONS.—



1 “(I) IN GENERAL.—The Sec-  
2 retary may provide an extension of  
3 the due date under clause (i)(I) for in-  
4 formation on the results of a clinical  
5 trial if the responsible person for the  
6 trial submits to the Secretary a writ-  
7 ten request that demonstrates good  
8 cause for the extension and provides  
9 an estimate of the date on which in-  
10 formation on the results will be sub-  
11 mitted. More than one such extension  
12 may be provided by the Secretary for  
13 the clinical trial involved.

14 “(II) EXTENSIONS REGARDING  
15 JOURNAL PUBLICATION.—

16 “(aa) ARTICLE UNDER CON-  
17 sideration FOR PUBLICA-  
18 tion.—With respect to the sub-  
19 mission of information on the re-  
20 sults of a clinical trial, the Sec-  
21 retary shall under subclause (I)  
22 provide an extension of 18  
23 months after the due date under  
24 clause (i)(I) (or if such an exten-  
25 sion previously has been pro-



1 vided, 18 months beginning upon  
2 the expiration of the most recent  
3 extension) if—

4 “(AA) the request  
5 under such subclause dem-  
6 onstrates that an article pro-  
7 viding the information de-  
8 scribed in subparagraph (B)  
9 has been submitted to a  
10 peer-reviewed scientific or  
11 academic journal for which  
12 references are included in  
13 MEDLINE, and the request  
14 demonstrates that the article  
15 is being considered by the  
16 journal for publication; and

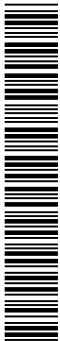
17 “(BB) such request is  
18 made before the expiration  
19 of the one-year period de-  
20 scribed in clause (i)(I) (or if  
21 such an extension previously  
22 has been provided, before  
23 the expiration of the most  
24 recent extension).



1                   “(bb) ARTICLE ACCEPTED  
2 FOR PUBLICATION.—If the re-  
3 sponsible person for a clinical  
4 trial has received an extension  
5 under item (aa) regarding the  
6 trial, the Secretary shall provide  
7 an additional extension of six  
8 months, beginning upon the expi-  
9 ration of such first extension, if  
10 the person demonstrates to the  
11 Secretary, before the expiration  
12 of the first extension, that the ar-  
13 ticle involved has been accepted  
14 for publication by a journal re-  
15 ferred to in such item.

16                   “(cc) PUBLICATION DURING  
17 PERIOD OF EXTENSION.—With  
18 respect to an extension under  
19 item (aa) or (bb), if during the  
20 period of extension the article in-  
21 volved is published in a journal  
22 referred to in item (aa)—

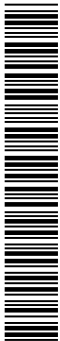
23                   “(AA) the extension  
24 terminates upon publication  
25 of the article; and



1 “(BB) the due date  
2 under clause (i) regarding  
3 the clinical trial involved be-  
4 comes the date of such pub-  
5 lication.

6 “(D) WAIVERS REGARDING RESULTS OF  
7 TRIAL.—With respect to the requirement under  
8 subparagraph (A) to submit to the Secretary in-  
9 formation on the results of a clinical trial, the  
10 Secretary may waive the requirement upon a  
11 written request to the Secretary by the respon-  
12 sible person for the trial if the Secretary deter-  
13 mines that extraordinary circumstances justify  
14 the waiver and that providing the waiver is in  
15 the public interest or consistent with the protec-  
16 tion of the public health. The Secretary shall  
17 ensure that information on each such waiver is  
18 included in the data bank.

19 “(3) UPDATES; TRACKING OF CHANGES IN SUB-  
20 MITTED INFORMATION.—The Secretary shall ensure  
21 that updates submitted to the Secretary under para-  
22 graphs (1)(A)(xvii) and (2)(B)(xii) do not result in  
23 the removal from the data bank of the original sub-  
24 missions or of any preceding updates, and that in-  
25 formation in the data bank is presented in a manner



1 that enables users to readily access each original  
2 submission and to track the changes made by the  
3 updates.

4 “(e) ENFORCEMENT.—

5 “(1) EFFECT OF FAILURE TO PROVIDE INFOR-  
6 MATION.—In the case of a clinical trial that is sub-  
7 ject to subsection (c)(1):

8 “(A) Subject to paragraph (2), if the Sec-  
9 retary determines that with respect to the trial  
10 the responsible person is not in compliance with  
11 requirements under subsection (d) to submit in-  
12 formation to the Secretary, the following ap-  
13 plies:

14 “(i) Such person is subject to a civil  
15 penalty in accordance with paragraph (3).

16 “(ii) The person is, during the period  
17 of such noncompliance, ineligible for any  
18 award from the Secretary of a grant, coop-  
19 erative agreement, or contract for the con-  
20 duct of any trial that is subject to sub-  
21 section (c)(1), including all current awards  
22 for such trials, except that such period of  
23 ineligibility may not exceed five years.

24 “(iii) The person is subject to the  
25 sanction described in paragraph (4) (relat-



1 ing to the investigational use of products)  
2 if the noncompliance is serious or repeated.

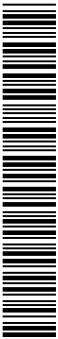
3 “(B) The submission to the Secretary of  
4 information under subsection (d) that is false or  
5 misleading constitutes noncompliance for pur-  
6 poses of subparagraph (A).

7 “(2) PROCEDURES REGARDING NONCOMPLI-  
8 ANCE.—

9 “(A) NOTICE OF NONCOMPLIANCE.—With  
10 respect to a clinical trial that is subject to sub-  
11 section (c)(1), if the Secretary determines that  
12 the responsible person involved has not sub-  
13 mitted information to the Secretary in accord-  
14 ance with subsection (d), the Secretary—

15 “(i) shall transmit to such person a  
16 notice specifying the required information  
17 and stating that the person will be subject  
18 to applicable sanctions referred to in para-  
19 graph (1)(A) if the information is not sub-  
20 mitted to the Secretary within 90 days  
21 after the date on which the notice is trans-  
22 mitted;

23 “(ii) shall through the notice inform  
24 the person that under subsection (h) the



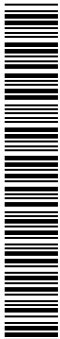
1 person is being identified in the data bank  
2 as a noncompliant person; and

3 “(iii) shall through the notice inform  
4 the person of the provisions of paragraph  
5 (8).

6 “(B) FAILURE TO CORRECT NONCOMPLI-  
7 ANCE.—Upon the expiration of the 90-day pe-  
8 riod beginning on the date on which the Sec-  
9 retary transmits a notice under subparagraph  
10 (A) to a responsible person, the Secretary shall  
11 impose on such person the sanctions referred to  
12 in clauses (i) and (ii) of paragraph (1)(A) if the  
13 information involved has not been submitted to  
14 the Secretary, except that the Secretary may  
15 elect not to impose such a sanction or sanctions  
16 if the Secretary determines that the noncompli-  
17 ance involved is not serious or repeated.

18 “(3) AMOUNT OF CIVIL PENALTY; HEARING  
19 PROCEDURES.—With respect to a civil penalty im-  
20 posed under paragraph (1)(A)(i) on a responsible  
21 person:

22 “(A) The amount of the penalty shall be  
23 not more than a total of \$15,000 for all viola-  
24 tions adjudicated in a single proceeding in the  
25 case of an individual, and not more than





1           \$10,000 per day until the violation is corrected  
2           in the case of any other person, except that if  
3           the person is a nonprofit entity the penalty may  
4           not exceed a total of \$15,000 for all violations  
5           adjudicated in a single proceeding.

6           “(B) The provisions of paragraphs (3)  
7           through (5) of section 303(f) of the Federal  
8           Food, Drug, and Cosmetic Act apply to the im-  
9           position of such a penalty to the same extent  
10          and in the same manner as such provisions  
11          apply to a penalty imposed under such section  
12          303(f).

13          “(4) ELIGIBILITY FOR INVESTIGATIONAL USE  
14          EXEMPTIONS.—In any case in which the noncompli-  
15          ance referred to in paragraph (1)(A) is serious or re-  
16          peated, the Secretary may, upon the expiration of  
17          the 90-day period beginning on the date on which  
18          the Secretary transmits a notice under paragraph  
19          (2)(A) to the responsible person involved, consider  
20          such person to be ineligible for any future exemp-  
21          tions under section 505(i) or 520(g) of the Federal  
22          Food, Drug, and Cosmetic Act for any investigation  
23          until the violation is corrected, except that such pe-  
24          riod of ineligibility may not exceed five years. The  
25          Secretary may impose such sanction only after no-

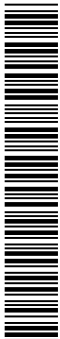


1       tice and an opportunity for a hearing, unless a hear-  
2       ing regarding such noncompliance is held pursuant  
3       to paragraph (3) and through such hearing the Sec-  
4       retary determines that the noncompliance was seri-  
5       ous or repeated.

6           “(5) FAILURE TO SUBMIT INFORMATION ON RE-  
7       SULTS; REQUIREMENT OF REPORTS.—In any case in  
8       which the noncompliance referred to in paragraph  
9       (1)(A) is a failure to submit to the Secretary infor-  
10      mation on the results of the trial by the due date  
11      under subsection (d)(2)(C)(i), the Secretary shall  
12      order the responsible person to submit to the Sec-  
13      retary periodic reports on the progress being made  
14      toward submission of information on the results,  
15      which reports shall be submitted not less frequently  
16      that once each year until the information is sub-  
17      mitted to the Secretary.

18           “(6) RULE OF CONSTRUCTION.—With respect  
19      to a responsible person who is subject to a sanction  
20      referred to in paragraph (1)(A), this subsection may  
21      not be construed as providing that any other person  
22      associated with the clinical trial involved is subject  
23      to the sanction.

24           “(7) USE OF FUNDS.—



1           “(A) IN GENERAL.—The Secretary shall  
2           deposit the funds collected under paragraph  
3           (1)(A) into an account and use such funds, in  
4           consultation with the Director of the Agency for  
5           Healthcare Research and Quality, to fund stud-  
6           ies that compare the clinical effectiveness of two  
7           or more treatments for a disease or condition.

8           “(B) FUNDING DECISIONS.—The Secretary  
9           shall award funding under subparagraph (A)  
10          based on a priority list established not later  
11          than six months after the date of enactment of  
12          the Fair Access to Clinical Trials Act by the  
13          Director of the Agency for Healthcare Research  
14          and Quality and periodically updated as deter-  
15          mined appropriate by the Director.

16          “(8) DISCLOSURE OF CERTAIN INFORMA-  
17          TION.—In the case of a responsible person to whom  
18          a notice under paragraph (2) has been transmitted,  
19          if such person has not submitted the information in-  
20          volved to the Secretary by the expiration of the 180-  
21          day period beginning on the date on which the notice  
22          was transmitted to the person, the following applies:

23               “(A) Notwithstanding section 301(j) of the  
24               Federal Food, Drug, and Cosmetic Act, section  
25               1905 of title 18, United States Code, subsection



1 (j)(4)(C)(ii) of this section, or any other provi-  
2 sion of law, the Secretary shall begin disclosure  
3 through the data bank of the definitions of the  
4 primary and secondary outcomes for the clinical  
5 trial involved unless the definitions have already  
6 been disclosed pursuant to subsection  
7 (j)(4)(C)(ii).

8 “(B) Notwithstanding section 301(j) of the  
9 Federal Food, Drug, and Cosmetic Act, section  
10 1905 of title 18, United States Code, or any  
11 other provision of law, if the responsible person  
12 is the manufacturer or a distributor of the  
13 product involved, the Secretary shall through  
14 the data bank disclose information on the prod-  
15 uct that—

16 “(i) is required to be submitted under  
17 subsection (d); and

18 “(ii) is included in any FDA applica-  
19 tion for the product (as defined in sub-  
20 section (l)) that the responsible person has  
21 submitted to the Secretary.

22 “(f) TRIALS CONDUCTED OUTSIDE UNITED  
23 STATES.—

24 “(1) IN GENERAL.—If a covered person submits  
25 to the Secretary an FDA application for a product



1 (as defined in subsection (l)), and one or more of the  
2 investigations presented to the Secretary by such  
3 person for purposes of the document are covered for-  
4 eign investigations, the person is subject to a civil  
5 penalty—

6 “(A) in any case in which information on  
7 the investigation has not, as of the date on  
8 which the application is submitted to the Sec-  
9 retary, been submitted to the data bank to the  
10 same extent as would have been required as of  
11 such date under subsection (d) if the investiga-  
12 tion had been subject to subsection (c)(1); and

13 “(B) in any case in which, after such date,  
14 information on the investigation is not sub-  
15 mitted to the data bank to the same extent as  
16 would be required if the investigation were sub-  
17 ject to subsection (c)(1).

18 “(2) PROCEDURES.—The provisions of para-  
19 graphs (2), (3), (6), and (7) of subsection (e) apply  
20 to a civil penalty under paragraph (1) to the same  
21 extent and in the same manner as such provisions  
22 apply to a civil penalty under subsection (e)(1)(A).

23 “(3) DEFINITIONS.—With respect to an FDA  
24 application for a product, for purposes of this sub-  
25 section:



1           “(A) The term ‘covered foreign investiga-  
2           tion’ means an investigation that was not con-  
3           ducted in any of the States and was not subject  
4           to subsection (c)(1).

5           “(B) The term ‘covered person’ means the  
6           person who was the principal investigator or the  
7           responsible person for any of the covered for-  
8           eign investigation or investigations involved.

9           “(g) LABELING AND ADVERTISEMENTS.—

10           “(1) IN GENERAL.—If a person disseminates la-  
11           beling, or an advertisement or other descriptive  
12           printed matter, for an approved product for human  
13           use and the labeling, advertisement, or other matter  
14           refers to an investigation that is not subject to sub-  
15           section (c)(1), and if the person was the principal in-  
16           vestigator or the responsible person for the inves-  
17           tigation, the person is subject to a civil penalty—

18           “(A) in any case in which information on  
19           the investigation has not, as of the date on  
20           which the labeling, advertisement, or other mat-  
21           ter enters the market, been submitted to the  
22           data bank to the same extent as would have  
23           been required as of such date under subsection  
24           (d) if the investigation had been subject to sub-  
25           section (c)(1); and



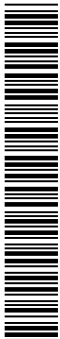
1           “(B) in any case in which, after such date,  
2           information on the investigation is not sub-  
3           mitted to the data bank to the same extent as  
4           would be required if the investigation were sub-  
5           ject to subsection (c)(1).

6           “(2) PROCEDURES.—The provisions of para-  
7           graphs (2), (3), (6), and (7) of subsection (e) apply  
8           to a civil penalty under paragraph (1) to the same  
9           extent and in the same manner as such provisions  
10          apply to a civil penalty under subsection (e)(1)(A).

11          “(h) PUBLIC LIST OF NONCOMPLIANT RESPONSIBLE  
12          PERSONS.—In any case in which a notice of noncompli-  
13          ance is submitted to a person under subsection (e)(2)(A),  
14          (f)(2), or (g)(2), the Secretary shall include with the infor-  
15          mation in the data bank that concerns the clinical trial  
16          involved a statement, prominently displayed, that such  
17          person has not reported information to the data bank as  
18          required by law, which statement shall remain in the data  
19          bank until the information involved is submitted to the  
20          Secretary. For purposes of the preceding sentence, the  
21          Secretary shall maintain a list of noncompliant persons  
22          that is available to the public.

23          “(i) COMPLIANCE AUDITS.—

24                 “(1) IN GENERAL.—The Secretary shall con-  
25          duct periodic audits of responsible persons for clin-



1        ical trials that are subject to subsection (c)(1) in  
2        order to determine whether such persons have sub-  
3        mitted information as required in subsection (d), in-  
4        cluding determining whether any of the information  
5        is false or misleading.

6            “(2) PRIORITY.—In conducting audits under  
7        subparagraph (A), the Secretary shall give priority  
8        to responsible persons for clinical trials who have at  
9        any time been included on the list under subsection  
10       (h), taking into account the number and severity of  
11       the violations involved.

12       “(j) GENERAL PROVISIONS.—

13            “(1) AUTHORITY OF SECRETARY.—

14            “(A) INCLUSION OF STATEMENTS TO  
15        AVOID MISINTERPRETATIONS.—The Secretary  
16        may include in the data bank such statements  
17        as the Secretary determines to be appropriate  
18        to assist the public in avoiding misinterpreta-  
19        tions of information in the data bank. State-  
20        ments under the preceding sentence may in-  
21        clude statements regarding the data bank in  
22        general and statements regarding particular  
23        items of information submitted to the data  
24        bank. The Secretary may not under the pre-





1 ceding sentence alter any information as sub-  
2 mitted.

3 “(B) FALSE OR MISLEADING INFORMA-  
4 TION.—If the Secretary determines that infor-  
5 mation presented or cited in the data bank is  
6 false or misleading, the Secretary shall, prompt-  
7 ly after making such determination, identify in  
8 the data bank the information as false or mis-  
9 leading (as applicable), and shall, to the extent  
10 practicable, include in the data bank an accu-  
11 rate version of the information. The Secretary  
12 shall in addition make appropriate public notifi-  
13 cation.

14 “(2) LIMITATION ON DISCLOSURES.—This sec-  
15 tion may not be construed as authorizing the disclo-  
16 sure of information through the data bank if—

17 “(A) such disclosure would constitute a  
18 clearly unwarranted invasion of personal pri-  
19 vacy; or

20 “(B) such information concerns a method  
21 or process which as a trade secret is entitled to  
22 protection within the meaning of section 301(j)  
23 of the Federal Food, Drug, and Cosmetic Act.

24 “(3) INSTITUTIONAL REVIEW BOARDS.—The  
25 Secretary shall amend part 46 of title 45, Code of



1 Federal Regulations, and parts 50, 56, and 812 of  
2 title 21 of Code, to provide as follows:

3 “(A) That the functions of institutional re-  
4 view boards under such parts include—

5 “(i) determining whether clinical trials  
6 that are subject to subsection (c)(1) are  
7 registered under subsection (d)(1)(A); and

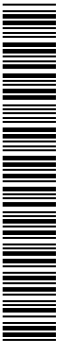
8 “(ii) denying the approval of the  
9 boards for such trials that are not so reg-  
10 istered.

11 “(B) That any approval of an institutional  
12 review board regarding such a trial is not effec-  
13 tive under such parts if the trial is not so reg-  
14 istered.

15 “(C) That upon request of an institutional  
16 review board for such a trial, the Secretary will  
17 provide to the board a copy of the registration  
18 for the trial under subsection (d)(1)(A) (which  
19 copy will be the registration as submitted to the  
20 Secretary, together with all updates to the reg-  
21 istration).

22 “(4) DISCLOSURE OF INFORMATION.—

23 “(A) IN GENERAL.—The Secretary shall  
24 disseminate information in the data bank  
25 through an Internet site or sites under subpara-



1 graph (B) and through any other means deter-  
2 mined appropriate by the Secretary. Informa-  
3 tion required in this section to be submitted to  
4 the Secretary shall not be considered confiden-  
5 tial commercial information or trade secrets,  
6 notwithstanding any other provision of law.

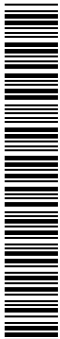
7 “(B) INTERNET SITES.—

8 “(i) IN GENERAL.—The Secretary  
9 shall operate one or more searchable Inter-  
10 net sites for purposes of presenting to cli-  
11 nicians and researchers, and to patients  
12 seeking to enroll as subjects in clinical  
13 trials, information in the data bank. The  
14 Secretary shall ensure that—

15 “(I) such a site, or a portion of  
16 a site, is designed specifically for use  
17 by clinicians and researchers; and

18 “(II) such a site, or a portion of  
19 a site, is designed specifically for use  
20 by patients seeking to enroll as sub-  
21 jects in clinical trials.

22 “(ii) RELATION TO CERTAIN INTER-  
23 NET SITE.—The Secretary shall ensure  
24 that the Internet site or portion thereof op-  
25 erated under clause (i)(II) includes infor-

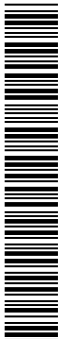


1           mation of the type that was available on  
2           ClinicalTrials.gov as of the day before the  
3           date of the enactment of the Fair Access  
4           to Clinical Trials Act (relating to serious  
5           or life-threatening diseases). This section  
6           may not be construed as requiring the Sec-  
7           retary to terminate or alter  
8           ClinicalTrials.gov, or as prohibiting the  
9           Secretary from terminating or altering  
10          such site.

11           “(C) REGISTRATION INFORMATION; DATE  
12          OF DISCLOSURE.—In the case of information  
13          regarding a clinical trial that is submitted to  
14          the Secretary under subsection (d)(1), disclo-  
15          sures of the information through the data bank  
16          shall, subject to subsection (e)(8), begin in ac-  
17          cordance with the following:

18               “(i) All such disclosures shall begin  
19               promptly after the registration involved is  
20               submitted to the Secretary, other than dis-  
21               closure of the definitions of the primary  
22               and secondary outcomes.

23               “(ii) Disclosure of the definition of  
24               the primary and secondary outcomes shall  
25               begin at the same time as disclosure of the



1 results of the trial begin under subpara-  
2 graph (D)(i), unless the responsible person  
3 for the trial requests earlier disclosure, or  
4 unless the Secretary requires earlier disclo-  
5 sure pursuant to subparagraph (E)(ii).

6 “(D) RESULTS OF TRIAL; DATE OF DIS-  
7 CLOSURE.—

8 “(i) IN GENERAL.—In the case of in-  
9 formation regarding a clinical trial that is  
10 submitted to the Secretary under sub-  
11 section (d)(2)(A), disclosures of the infor-  
12 mation through the data bank shall begin  
13 promptly after the information is sub-  
14 mitted to the Secretary, subject to clause  
15 (ii).

16 “(ii) WAIVER REGARDING RESULTS  
17 OF TRIAL.—In the case of information on  
18 waivers that is contained in the data bank  
19 under subsection (d)(2)(D), disclosures of  
20 the information through the data bank  
21 shall begin promptly after the waiver is  
22 provided.

23 “(E) STUDY REGARDING DATE FOR DIS-  
24 CLOSURE OF PRIMARY AND SECONDARY OUT-  
25 COMES; AUTHORITY OF SECRETARY.—



1           “(i) IN GENERAL.—The Secretary, in  
2           consultation with appropriate government  
3           agencies, shall conduct a study to deter-  
4           mine whether the delay in disclosure of the  
5           definitions of the primary and secondary  
6           outcomes under clause (ii) of subparagraph  
7           (C), relative to the timing of disclosures  
8           under clause (i) of such subparagraph, is  
9           consistent with the protection of the public  
10          health. Not later than three years after the  
11          date of the enactment of the Fair Access  
12          to Clinical Trials Act, the Secretary shall  
13          complete the study and submit to the ap-  
14          propriate committees of the Congress a re-  
15          port describing the findings of the study.

16          “(ii) AUTHORITY OF SECRETARY.—If  
17          on the basis of the study under clause (i)  
18          the Secretary determines that the delay re-  
19          ferred to in such clause is not consistent  
20          with the protection of the public health,  
21          the Secretary shall by regulation establish  
22          an earlier date for disclosures of the defini-  
23          tions referred to in such clause, which date  
24          may not be earlier than the date of disclo-  
25          sures under subparagraph (C)(i). A final



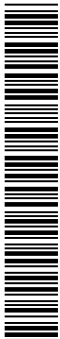
1 rule shall be issued under the preceding  
2 sentence not later than one year after the  
3 date on which the report under clause (i)  
4 of this subparagraph is submitted to the  
5 appropriate committees of the Congress.

6 “(5) LIMITATION ON USE OF INFORMATION.—  
7 Information on a clinical trial that is disclosed  
8 through the data bank, including information dis-  
9 closed under subsection (e)(8), may not be used by  
10 a person other than the responsible person for the  
11 trial (or an entity acting with the permission of such  
12 person) as part of any FDA application (as defined  
13 in subsection (l)) unless the information is available  
14 in accordance with law from a source other than the  
15 data bank.

16 “(6) SUBMISSION FORMAT AND TECHNICAL  
17 STANDARDS.—

18 “(A) IN GENERAL.—The Secretary shall,  
19 to the extent practicable, accept submissions re-  
20 quired in subsection (d) in an electronic format  
21 and shall establish interoperable technical  
22 standards for such submissions.

23 “(B) CONSISTENCY OF STANDARDS.—To  
24 the extent practicable, the standards established  
25 under subparagraph (A) shall be consistent



1 with standards adopted by the Consolidated  
2 Health Informatics Initiative (or a successor or-  
3 ganization to such Initiative) to the extent such  
4 Initiative (or successor) is in operation.

5 “(7) TRIALS NOT INVOLVING DRUGS, BIOLOGI-  
6 CAL PRODUCTS, OR DEVICES.—The Secretary shall  
7 establish procedures and mechanisms to allow for  
8 the voluntary submission to the Secretary of infor-  
9 mation described in subsection (d)(2)(B) on clinical  
10 trials that are not subject to subsection (c)(1). Infor-  
11 mation received by the Secretary under this para-  
12 graph shall be included in the data bank. In any  
13 case in which it is in the interest of public health,  
14 the Secretary may require that information on such  
15 trials be submitted to the Secretary. Failure to com-  
16 ply with such a requirement shall be deemed to be  
17 a failure to submit information as required under  
18 this section, and the appropriate remedies and sanc-  
19 tions under this section shall apply.

20 “(8) AWARD FOR CONDUCT OF CLINICAL TRIAL;  
21 COMPLIANCE COSTS AS DIRECT COSTS.—In admin-  
22 istering an award of a grant, contract, or coopera-  
23 tive agreement that is subject to subsection (c)(1),  
24 the Secretary shall consider the costs of complying





1 with requirements under this section as part of the  
2 direct costs of conducting the clinical trial involved.

3 “(k) CRITERIA.—The Secretary shall establish cri-  
4 teria regarding compliance with this section.

5 “(l) DEFINITIONS.—For purposes of this section:

6 “(1) The term ‘approved product’ means a  
7 product that is approved, licensed, or cleared for  
8 commercial distribution under section 505, 510(k),  
9 or 515 of the Federal Food, Drug, and Cosmetic Act  
10 or under section 351 of this Act.

11 “(2) The term ‘approved use’, with respect to  
12 an approved product, means a use that is an ap-  
13 proved, licensed, or cleared use of the product under  
14 a provision of law referred to in paragraph (1).

15 “(3) The term ‘biological product’ has the  
16 meaning given such term in section 351.

17 “(4) The term ‘classified’, with respect to infor-  
18 mation, means information on matters referred to in  
19 section 552(b)(1)(A) of title 5, United States Code.

20 “(5) The term ‘clinical trial’, with respect to a  
21 product, means a clinical investigation within the  
22 meaning of section 505(i) of the Federal Food,  
23 Drug, and Cosmetic Act (in the case of drug), or  
24 within the meaning of section 520(g) of such Act (in  
25 the case of a device), as applicable, except that such



1 term does not include such an investigation that  
2 does not prospectively assign human subjects to  
3 intervention or comparison groups to study the caus-  
4 al relationship between a medical intervention and  
5 an outcome.

6 “(6) The term ‘data bank’ means the data bank  
7 under subsection (a).

8 “(7) The term ‘device’ has the meaning given  
9 such term in section 201(h) of the Federal Food,  
10 Drug, and Cosmetic Act.

11 “(8) The term ‘drug’ has the meaning given  
12 such term in section 201(g)(1) of the Federal Food,  
13 Drug, and Cosmetic Act. Such term includes a bio-  
14 logical product.

15 “(9) The term ‘FDA application’, with respect  
16 to a product, means each of the following:

17 “(A) An application or report submitted to  
18 the Secretary for the purpose of seeking a deci-  
19 sion by the Secretary for the product to become  
20 an approved product (as defined in paragraph  
21 (1)). Such term includes a supplement to such  
22 an application or report.

23 “(B) An application for an exemption  
24 under section 505(i) or 520(g) of the Federal



1 Food, Drug, and Cosmetic Act (relating to in-  
2 vestigational use).

3 “(10) The term ‘MEDLINE’ means the biblio-  
4 graphic electronic data base of references to journal-  
5 published articles that is operated by the National  
6 Library of Medicine and is designated by such Li-  
7 brary as the Medical Literature, Analysis, and Re-  
8 trieval System Online.

9 “(11) The term ‘postmarket’, with respect to a  
10 clinical trial to investigate a product, means a clin-  
11 ical trial that is conducted after the product has be-  
12 come an approved product.

13 “(12) The term ‘product’ means a drug, biologi-  
14 cal product, or device.

15 “(13) The term ‘responsible person’, with re-  
16 spect to a clinical trial that is subject to subsection  
17 (c)(1), has the following meaning, as applicable:

18 “(A) In any case in which an application  
19 has with respect to the trial been submitted for  
20 an exemption under section 505(i) or  
21 520(g)(2)(A) of the Federal Food, Drug, and  
22 Cosmetic Act, such term means the entity who,  
23 within the meaning of such section, is the spon-  
24 sor of the trial.



1           “(B) In any case in which such an applica-  
2           tion has not been submitted, such term means  
3           the entity who is or will be providing the largest  
4           share of the monetary support for the trial  
5           (without regard to any in-kind support for the  
6           trial), subject to the following:

7                   “(i) If the Federal Government or a  
8                   State is or will be providing the largest  
9                   share, such term means the principal in-  
10                  vestigator for the trial.

11                   “(ii) If a nonprofit private entity is or  
12                   will be providing the largest share, such  
13                   term means the principal investigator for  
14                   the trial in any case in which such entity  
15                   and investigator have jointly certified to  
16                   the Secretary that the investigator will be  
17                   the responsible person for purposes of this  
18                   section.

19                   “(iii) If two or more entities provide  
20                   equal monetary support for the trial and  
21                   no other entity provides a greater amount  
22                   of monetary support, such term means  
23                   each of the entities providing such equal  
24                   support, other than the Federal Govern-  
25                   ment or a State.



1                   “(iv) Notwithstanding clauses (i)  
2                   through (iii), if an entity submits to the  
3                   Secretary a written request to be the re-  
4                   sponsible person for purposes of this sec-  
5                   tion, such term means that entity in any  
6                   case in which the Secretary determines  
7                   that the entity is responsible for con-  
8                   ducting the trial, has access to and control  
9                   over the data, has the right to publish the  
10                  results of the trial, and has the responsi-  
11                  bility to meet all of the requirements under  
12                  this section that are applicable to respon-  
13                  sible persons.

14               “(14) The term ‘unapproved product’ means a  
15               product that is not an approved product.

16               “(15) The term ‘unapproved use’, with respect  
17               to an approved product, means a use that is not an  
18               approved use.

19               “(m) AUTHORIZATION OF APPROPRIATIONS.—For  
20               the purpose of carrying out this section, there are author-  
21               ized to be appropriated such sums as may be necessary  
22               for fiscal year 2005 and each subsequent fiscal year. Fees  
23               collected under section 736 or 738 of the Federal Food,  
24               Drug, and Cosmetic Act shall not be used in carrying out  
25               this section.”.

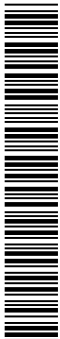


1 (b) APPLICABILITY.—With respect to section 402A of  
2 the Public Health Service Act (as added by subsection (a)  
3 of this section):

4 (1) Subject to paragraphs (2) and (3), such  
5 section 402A applies to all clinical trials that are  
6 commenced on or after the date of the enactment of  
7 this Act, or are in progress as of such date, to the  
8 extent the trials are described in subsection (c)(1) of  
9 such section and not within an exception under sub-  
10 section (c)(2) of such section.

11 (2) For purposes of paragraph (1), such section  
12 402A applies to a trial that is in progress only if the  
13 final data collection from subjects in the trial on the  
14 primary outcome has not been completed as of the  
15 date of the enactment of this Act. Such a trial be-  
16 comes subject to such section upon the expiration of  
17 30 days after such date of enactment, except that  
18 registration information required pursuant to sub-  
19 section (d)(1) of such section is due upon the expira-  
20 tion of such 30 days.

21 (3) The Secretary of Health and Human Serv-  
22 ices (referred to in this paragraph as the “Sec-  
23 retary”) shall establish procedures and mechanisms  
24 to allow for the voluntary submission to the Sec-  
25 retary of information described in subsection

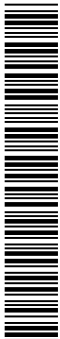


1 (d)(2)(B) of such section 402A on clinical trials that  
2 were completed prior to such date of enactment, or  
3 were in progress as of such date but not subject to  
4 paragraph (2). Information received by the Sec-  
5 retary under this paragraph shall be included in the  
6 data bank. In any case in which it is in the interest  
7 of public health, the Secretary may require that in-  
8 formation on such trials be submitted to the Sec-  
9 retary. Failure to comply with such a requirement  
10 shall be deemed to be a failure to submit informa-  
11 tion as required under such section, and the appro-  
12 priate remedies and sanctions under such section  
13 shall apply.

14 (4) Definitions applicable to such section 402A  
15 apply for purposes of this subsection.

16 (c) RULE OF CONSTRUCTION REGARDING PRIOR  
17 PROVISION.—With respect to the data bank program  
18 under section 402(j) of the Public Health Service Act as  
19 in effect on the day before the date of the enactment of  
20 this Act:

21 (1) Subsection (a) shall be construed as a  
22 transfer and modification of the program, and not as  
23 the termination of the program and the establish-  
24 ment of a different program.



1           (2) All information contained in the data bank  
2           on such day shall continue to be contained in the  
3           data bank, subject to section 402A of the Public  
4           Health Service Act (as added by subsection (a) of  
5           this section) or other applicable provisions of law.

6           (d) CONFORMING AMENDMENTS.—Chapter V of the  
7           Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351  
8           et seq.) is amended—

9           (1) in section 505(i), by adding at the end the  
10          following paragraph:

11          “(5) The provision of an exemption under paragraph  
12          (1) is subject to section 402A(e)(4) of the Public Health  
13          Service Act (relating to a data bank on clinical trials).”;  
14          and

15          (2) in section 520(g), by adding at the end the  
16          following paragraph:

17          “(8) The provision of an exemption under paragraph  
18          (2)(A) is subject to section 402A(e)(4) of the Public  
19          Health Service Act (relating to a data bank on clinical  
20          trials).”.

21       **SEC. 3. REPORTS.**

22          (a) IMPLEMENTATION REPORT.—Not later than one  
23          year after the date of enactment of this Act, the Secretary  
24          of Health and Human Services (referred to in this section  
25          as the “Secretary”) shall submit to the appropriate com-





1 mittees of the Congress a report on the status of the im-  
2 plementation of the requirements of the amendments  
3 made by section 2 that includes a description of the num-  
4 ber and types of clinical trials for which information has  
5 been submitted under such amendments.

6 (b) DATA COLLECTION.—

7 (1) IN GENERAL.—The Secretary shall request  
8 the Institute of Medicine to enter into a contract  
9 with the Secretary for the conduct of a study con-  
10 cerning the extent to which information submitted to  
11 the data bank under section 402A of the Public  
12 Health Service Act (as added by section 2(a)) has  
13 impacted the public health.

14 (2) REPORT.—The Secretary shall ensure that  
15 the contract under paragraph (1) provides that, not  
16 later than six months after the date on which a con-  
17 tract is entered into, the Institute of Medicine will  
18 submit to the Secretary a report on the results of  
19 the study under such paragraph, and that the report  
20 may include any recommendations of the Institute  
21 for changes to the program carried out under the  
22 section referred to in such paragraph that the Insti-  
23 tute considers appropriate to benefit the public  
24 health.

